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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,060	11/25/2003	Donal Coveney	TOMK-0001 (122359.00003)	4165
7590	08/24/2004		EXAMINER	
T. Ling Chwang Suite 600 2435 N. Central Expressway Richardson, TX 75080			OH, TAYLOR V	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/722,060	Applicant(s) COVENEY ET AL.	
	Examiner Taylor Victor Oh	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3 is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1625

The Status of Claims:

Claims 1-14 are pending.

Claims 1-2 and 4-14 have been rejected.

Claim 3 is allowable.

DETAILED ACTION

Priority

1. None.

Drawings

2. None.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2 and 4-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the phrase "at least one R_1 is H and the remainder are CH_2CO_2K " is recited. The expression is vague and infinite because there are many kinds of R_1 group, which are not described in the claim; also, the term "the remainder" is uncertain

Art Unit: 1625

as to what it is referred to (e.g. the remainder for which group). Therefore, an appropriate correction is required.

In claims 4, 12, and 13, the phrase "having different degrees of alkylation" is recited. The expression is vague and infinite because the examiner may wonder how many different degrees of alkylation can be formed in the compounds of formula I. Therefore, an appropriate correction is required.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, claims 5 and 6 recite the broad recitation of viral infection, and the claims also recite "particularly HIV-1 infection", which is the narrower statement of the range/limitation. Therefore, an appropriate correction is required.

Art Unit: 1625

Claims 4 ,8-9 and 13 recite the limitation "formula I" in " formula I having different degrees of alkylation". There is insufficient antecedent basis for this limitation in the claims.

Claims 5 and 6 provide for the "use of a compound as claimed in any one of claims 1 to 3", but, since the claims does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 5 and 6 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 7 recites the limitation "formula I or II" in "formula I or II as defined herein". There is insufficient antecedent basis for this limitation in the claim.

Claims 10 and 11 recite the limitation "formula I" in " formula I comprising the steps ". There is insufficient antecedent basis for this limitation in the claims.

Claim 12 recites the limitation "formula I or II " in " at least one compound of formula I or II ". There is insufficient antecedent basis for this limitation in the claim.

Claims 12 and 14 recite the limitation "formula I or II" or a mixture of compounds of formula I" in " formula I having different degrees of alkylation". There is insufficient antecedent basis for this limitation in the claims.

In claims 12-14, the phrase " A method of treatment of infection " is recited. The expression is vague and infinite because there are many different types of infections, such as bacterial , fungal, viral infection, and etc; the claims do not describe what kinds of infection is referred to. Therefore, an appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated clearly by Harris (WO 95/19974).

Harris discloses the preparation of pyrogallol-aldehyde cyclic tetramers and derivatives (examples 184 and 185) by the reaction of n-butyraldehyde and pyrogallol in 1 : 4 with HCl under nitrogen (see, page 45, example 163 , lines 30-34), and the

Art Unit: 1625

reaction mixture is further etherified with ethyl bromoacetate and potassium carbonate in acetone (see, page 46, example 165 , lines 5-9), and then further treated with potassium hydroxide in ethanol in order to obtain the desired product(see, page 45, example 169 , lines 30-35). This is identical with the claim.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

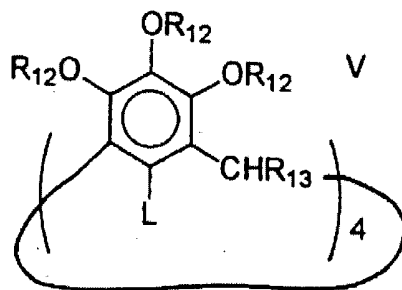
Art Unit: 1625

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

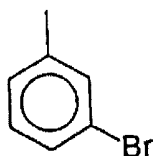
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2, 4-10, and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harris (WO 95/19974) in view of Aldrich (page 811, 1999).

Harris teaches cyclic tetrameric pyrogallol-aldehyde derivatives of the following compounds (see page 8, lines 14-36) :



wherein R_{12} is H or $\text{CH}_2\text{CO}_2\text{M}$ (M is metal ion) (see page 7, line 31); L is halogen, H, or other electron withdrawing group; and R_{13} is



Art Unit: 1625

The invention further provides pharmaceutical compositions comprising a pharmaceutically effective amount of any of the above defined compounds, either singly or in combination. The invention also provides use of any of the above defined compounds, either singly or in combination, in the preparation of a medicament for the treatment of bacterial infection, fungal infection or viral infection, particularly HIV-1, HIV-2 or SIV infection. The invention also provides a method of medical treatment comprising administering a therapeutically effective amount of any of the above defined compounds to a patient, either singly or in combination.
(see page 13 , lines 11-20).

Furthermore, Harris discloses the preparation of pyrogallol-aldehyde cyclic tetramers and derivatives (see page 122, examples 184 and 185) by the reaction of m-bromobenzaldehyde and pyrogallol (see page 49, example 181) in 1 : 4 with HCl under nitrogen (see, page 45, example 163 , lines 30-34), and the reaction mixture is further etherified with ethyl bromoacetate and potassium carbonate in acetone (see, page 46, example 165 , lines 5-9), and then further treated with potassium hydroxide in ethanol in order to obtain the desired product(see, page 45, example 169 , lines 30-35).

However, the instant invention differs from the prior art in that the claimed R₂ group is para-fluorobenzene instead of the meta-bromobenzene group.

Even so, the substituent on the benzene ring in the prior art and the instant invention is belonged to the halogen family in which the bromine and the fluorine have a similar reactivity between them; furthermore, they are related to each other with

Art Unit: 1625

respect to the positional isomers. It is obvious to the skilled artisan in the art to be motivated to substitute the known fluoride group to the para-position instead of the meta position of the benzene group in the absence of an unexpected result.

Harris expressly teaches the method of producing the cyclic tetrameric pyrogallol-aldehyde derivatives having the meta-bromobenzene group as the R_2 group by reaction of m-bromobenzaldehyde and pyrogallol (see page 49, example 181). The reactivity between the bromine and the fluorine is similar to each other because of the same periodic family; also, they are in a positional isomer-relationship. Moreover, the p-fluorobenzaldehyde is well-known compound in the art as shown in Aldrich (page 811, 1999). Therefore, if the skilled artisan in the art had desired to make the cyclic tetrameric pyrogallol-aldehyde derivatives having the para-fluorobenzene group as the R_2 group, it would have been obvious to the skilled artisan in the art to be motivated to use the Aldrich's p-fluorobenzaldehyde as the starting material in the Harry's process as an alternative because the skilled artisan in the art would expect such a modification to be successful as shown in the Harry process due to the equivalency of their reactivity between the bromine and the fluorine substituents.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached from 8:30-5:00.

Art Unit: 1625

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*** *[Signature]* 8/19/04

[Signature]
8/20/04

RITA DESAI
PRIMARY EXAMINER